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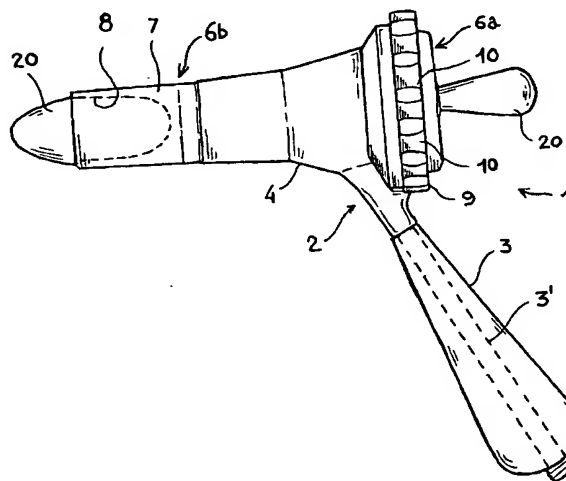
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(54) Title: ROTATING OPERATING ANOSCOPE



(57) Abstract: An anoscope (1), comprising a first hollow-body means (4) open at opposite ends and a second hollow-body means (6) open at opposite ends shapingly coupled with said first hollow-body means (4) and arranged to coaxially rotate inside said first hollow-body means (4), said second hollow-body means (6) being provided with a window means (8) arranged to make of portion of rectal mucous accessible, characterised in that: said window means (8) has dimensions and a shape such as to enable surgical means to intervene on said portion; angular positioning means (9) is arranged to regulate the corner position of said second hollow-body means (6) in said first hollow-body means (4) in preset reciprocal angular positions.

WO 2004/021874 A1

Rotating operating anoscope

The present invention concerns an anoscope that can be used in proctology as a diagnostic and/or surgical instrument, said anoscope being provided with a guided-rotation device that is particularly useful for carrying out surgical treatment of haemorrhoids.

Anoscopes are prior-art instruments that are used in general medicine, gastroenterology, proctology, endoscopy and general surgery.

A generic anoscope usually comprises a portion called "speculum", having a cylindrical or tapered-cylindrical shape, that can be handled by an operator by a grip and that is arranged to be inserted through the anus into the terminal segment of the rectum of a patient. The speculum is hollow, open at opposite ends, and is inserted together with a dilator that has a cylindrical shape with a rounded end and which is provided with a smooth surface, and is furthermore substantially longer than the speculum. The dilator is accommodated inside the speculum during the insertion manoeuvre and acts by distending the muscular wall of the rectum without harming the mucous membrane thereof. Once the manoeuvre has been completed the dilator is extracted whilst the speculum remains in place.

In this way temporary dilatation that is restricted to the terminal segment of the intestinal lumen is obtained, and such dilatation can be used to easily insert further instruments and thus carry out diagnostic and/or surgical operations.

One of the methods for surgically treating haemorrhoids involves obliterating the arterial branches that are afferent to them, i.e. binding through suturing the walls of these vessels in such a way as to form a constriction that interrupts the blood flow towards the haemorrhoids.

For this purpose anoscopes are used wherein the above-mentioned speculum has a cut on its side wall in such a way as

to create an 'operating window' through which surgical instruments (forceps, suture needle holders) come into contact with the intestinal mucous membrane in proximity to the operating site, taking advantage of the fact that the mucous membrane protrudes inside the speculum at the above-mentioned window.

One disadvantage of said anoscopes consists of the fact that the operating window opens on a set area of the speculum. If, as generally happens, a surgeon has to treat several haemorrhoids in a same patient during a single operation, the speculum must be rotated so as to reposition the window near the arterial branch concerned. To carry out this manoeuvre, it is necessary to first insert the previously described dilator to distend the rectal mucous membrane at the operating window and thereby prevent the mucous membrane being 'pinched' in the window during shifting of the latter. The speculum is then gripped and it is rotated around its longitudinal axis according to a rotation angle that is such as to place the window in the desired position.

Obviously, such manoeuvres lengthen the duration of the operation for the surgeon and therefore subject the patient undergoing the surgery to greater distress.

US 6126594 discloses an anoscope that can be used to treat hemorrhoids and which is characterised by the presence of a plurality of openings arranged parallel to one another in the body of the speculum, in such a way as to provide a surgeon with a multiplicity of operating windows that can be used simultaneously. In practice, such device has the disadvantage that the rectal mucous membrane may simultaneously protrude into a plurality of zones, thereby obstructing the internal cavity of the speculum, i.e. the field of operation itself.

Anoscopes have also been created (see for example the "Welch Allyn" model 38850/38900), wherein the speculum is movable, being hinged on a fixed portion and therefore being rotatable

around its own longitudinal axis. Such anosscopes are, however, made for merely diagnostic purposes, i.e. in order to enable a 360° view of the lumen of the rectum and are provided with a window that extends over the entire length of the part of the body of the speculum that is inserted (i.e. that portion of speculum that is actually inserted into the rectal canal).

This technical expedient is certainly useful for exploring the terminal segment of the intestinal cavity without neglecting any area of the mucous membrane, but which causes a massive protrusion of the mucous membrane itself within the speculum that is due to the dimensions of the window. As has already been said, a such phenomenon is disadvantageous during a surgical operation because it causes undesired visual and material obstruction of the operating area.

Furthermore, new surgical techniques are becoming widespread for performing which the prior-art instruments are not always suitable. For example, Dr Francesco Sias (Santa Rita Clinic, Cagliari) recently perfected a method (haemorrhoidal dearterialization with transanal anopexy) that enables haemorrhoids to be treated surgically in a day hospital, that can be carried out without anaesthesia. Such method is based on an anatomical feature, i.e. on the constant presence (documented by Doppler echography) of 6 terminal arterial branches coming from the lower haemorrhoidal artery, said arterial branches being arranged along the wall of the rectum according to a precise geometry and at the end of which the haemorrhoids appear.

In fact, by arranging a patient in a prone position, so as to have the anal opening arranged frontally, the above-mentioned 6 arterial branches are placed on an imaginary clock-face at 1 o'clock, at 3 o'clock, at 5 o'clock, at 7 o'clock, at 9 o'clock, at 11 o'clock. The surgeon may thus make a ligature of said arterial branches (through a so-called "Z" suture) by intervening above the haemorrhoids. Furthermore, the region of

mucous membrane of the rectum subjected to the operation is substantially devoid of sensitive nerves, thus making local anaesthesia unnecessary. Such an operation enables operating time to be halved compared with other types of surgical treatment of haemorrhoids and does not require the patient to be admitted as an inpatient.

However, this method requires a plurality of sutures to be carried out in preset positions.

It is obvious that none of the anosopes disclosed up until now is ideal for the application of the method. In fact, by using an anoscope with a single window the instrument has to be rotated six times during the operation, with the disadvantages illustrated previously. It would be similarly disadvantageous to use an anoscope with multiple windows or a rotating anoscope, because in both cases the intestinal mucous membrane would take up an undesirable amount of space in the field of operation.

In addition, it should be added that none of the above-mentioned instruments is provided with devices that help the surgeon to position the operating window exactly at the arterial branch that is to be sutured.

An aim of the present invention is to improve the anosopes that can be used in operating practice.

A further aim is to provide an anoscope equipped with operating windows that can be positioned near the arterial branches to be treated without having to rotate the entire instrument.

Another aim is to provide operating windows of dimensions such as to make accessible only the portions of rectal mucous membrane that are actually concerned by the surgical treatment.

Another further aim is to provide an anoscope that is more compact, which is useful during transport and/or storage.

Yet another further aim is to provide an anoscope that enables an operating window to be rapidly and exactly positioned during the performance of a method for treating haemorrhoids involving suturing arterial branches located in known positions in relation to the axis of the rectum.

In a first aspect of the invention an anoscope is provided, comprising a first hollow-body means open at opposite ends and a second hollow-body means open at opposite ends shapingly coupled with said first hollow-body means and arranged to coaxially rotate inside said first hollow-body means, said second hollow-body means being provided with a window means arranged to make a portion of rectal mucous membrane accessible, characterised in that said window means has dimensions and a shape such as to enable surgical means to intervene on said portion.

An anoscope conceived in this manner enables an operating window to be subsequently positioned at different points of the rectal mucous membrane by acting simply on a part of the anoscope and without having to rotate the entire instrument.

Advantageously, the operating window is of dimensions such as to ensure access only to the areas of the rectal mucous membrane that are actually concerned by the treatment, thereby avoiding the protrusion into the hollow-body means of excessive portions of mucous membrane, with consequent take-up of space in the field of operation.

Also advantageously, the first hollow-body means comprises a grip that facilitates the insertion of the anoscope in the rectal canal and can accommodate a light-beam means to enable illumination of the field of operating.

In a further advantageous manner, the second hollow-body means may comprise two separate segments that can be associated to each other before use in such a way as to be able to reduce the dimensions of the anoscope during transport and storage.

In a second aspect of the invention an anoscope is provided, comprising a first hollow-body means open at opposite ends and a second hollow-body means open at opposite ends shapingly coupled with said first hollow-body means and arranged to coaxially rotate inside said first hollow-body means, said second hollow-body means being provided with a window means arranged to make a portion of rectal mucous membrane accessible, characterised in that an angular positioning means is furthermore provided arranged to adjust the relative angular position of said second hollow-body means in said first hollow-body means in preset reciprocal angular positions.

Advantageously, said angular positioning means comprises an adjusting ring nut that controls 360° rotation of said second hollow-body means, enabling the latter to be locked in six alternative positions, corresponding to the same number of positions taken up by the operating window in relation to the internal rectum wall. Said positions are the same as the ones indicated by the Sias method for surgical treatment of haemorrhoids disclosed above.

In order that the invention may be clearly and completely disclosed, reference will now be made, by way of examples that do not limit the scope of the invention, to the accompanying drawings, wherein

Fig. 1 shows a rotating operating anoscope according to the invention, complete with dilator;

Figs. 2 to 7a show the individual elements making up the anoscope in Fig. 1, namely:

Fig. 2 is a side view of the fixed portion of the anoscope, complete with a grip for the operator;

Fig. 3 is a side view of the segment of movable portion of the anoscope not comprising the operating window;

Figs. 4A and 4B are two different side views of the segment of movable portion of the anoscope comprising the operating window;

Fig. 5 is a side view of the dilator contained in the anoscope in Fig. 1;

Fig. 6 is an incomplete front view of the fixed portion shown in Fig. 2;

Fig. 7 is a front view of the segment of movable portion shown in Fig. 3;

Fig. 7A is an enlarged detail illustrating a device comprised in the segment of movable portion shown in Fig. 7.

Fig. 8 is an interrupted side view of the anoscope, showing the positioning mechanism of the operating window.

With reference to Figures 1 and 2, a rotating operating anoscope 1 comprises a fixed portion 2, comprising in turn a grip 3 that is joined to a support element 4, made of a material that can be sterilised, for example steel, and arranged to penetrate the rectal canal through the anal orifice. The grip 3 internally comprises a coaxial optic guide 3' (indicated by a broken line) arranged to accommodate a light-beam means (not indicated) that can be used to illuminate the field of operation, i.e. the internal cavity of the anoscope 1.

The support element 4 comprises a first truncated-cone portion 4a, a second truncated-cone portion 4b and a third truncated-cone portion 4c, that are joined together and internally hollow. The above-mentioned truncated-cone portions have diameters that decrease from the first truncated-cone portion 4 to the third truncated-cone portion 4c, so that the end of the support element 4 comprising the base of the truncated-cone portion 4a has a diameter that is noticeably greater than the diameter of the end opposite the support element 4, comprising the truncated-cone portion 4c.

With reference to Figure 6, the above-mentioned base of the truncated-cone portion 4a, which corresponds to the end of the anoscope 1 facing the operator during use, comprises an edge 4'a that houses a plurality of notches 5. More exactly, there are 6 notches arranged at regular intervals along the edge 4'a. By making the edge 4'a coincide with the circular perimeter of an imaginary clock-face, the positions of the 6 notches correspond to the hours: 1, 3, 5, 7, 9, 11.

With reference to Figures 1, 3, 4A and 4B, a movable portion 6 is provided, comprising a rotation segment 6a and an operating segment 6b, both of which are hollow and are made of a disposable plastic material. The two segments can be associated together through a female thread F (indicated by a broken line) comprised in the base of the operating segment 6b and housing a corresponding thread F' comprised in the rotation segment 6a. The rotation segment 6a is shapingly coupled with the support element 4 in such a way that it can be inserted inside the latter. Once the movable portion 6 has been assembled it can be inserted inside the support element 4 and rotate coaxially by 360° in relation to the latter. The rotation segment 6a is made in such a way as to enable the operating segment 6b to protrude outside the support element 4. The operating segment 6b is a hollow cylinder that is open at opposite ends and has a side wall 7 interrupted by an operating window 8. The latter is delimited by a U-shaped cut, the convex part of which reaches near the female thread F. The operating window 8 is made in such a way that the convex end of the U-shaped cut corresponds to the point that can be reached by the end of the index finger of the hand of a person of average build by inserting the index finger inside the anoscope. In this way the operating window 8 constitutes the area where the operator can enter in direct contact with the rectal mucous membrane to carry out the "Z" surgical sutures provided by the Sias method.

With reference to Figures 1, 3, 7 and 7A the movable portion 6 comprises a positioning element 9 that is integral with the rotation segment 6a and is positioned in such a way as to face the operator during use. The positioning element 9 is shaped in the form of a ring comprising a plurality of teeth 10, arranged to facilitate the operator's grip of said toothed element. The teeth 10 comprise a locking tooth 10' (shown enlarged in detail 7A), that is marked by a navigator 30 and comprises a recess 11 housing a peg 11'. Between the bottom of the recess 11 and the end of the peg 11' next to said bottom a coil spring 12 is placed by which the peg 11' protrudes outside the recess 11. When the anoscope 1 is assembled, as the positioning element 9 is juxtaposed on the edge 4'a comprised in the support element 4 and as the recess 11 is arranged in such a way that the protruding end of the peg 11' comes into contact with said edge, the peg 11' is forced to retract completely into the recess 11, thereby compressing the spring 12. By rotating the positioning element 9 by 360° in relation to the fixed portion 4, the locking tooth 10' subsequently comes into contact with each of the notches 5 comprised in the edge 4'a. At each notch 5, the peg 11' can emerge from the recess 11, assisted by the relaxation of the spring 12, and partially penetrates inside the notch 5. In this way the positioning element 9, and therefore the movable portion 6, can be locked in each of the 6 positions defined by the notches 5. By slightly forcing the positioning element 9 it can be released and further rotated until it reaches the next notch 5.

The 6 fixed positions that can be reached by the locking tooth 10' correspond to analogous positions of the operating window 8 in relation to the internal wall of the rectum. If for example, as illustrated in Figure 8, the operator rotates the positioning element 9 until the locking tooth 10' fits in the notch 5 corresponding to 9 o'clock, the simultaneous rotation

of the movable portion 6 also places the operating window 8 in the position corresponding to 9 o'clock. In this manner, the operator, by orienting the anoscope with the grip parallel to the intergluteal sulcus of a patient, can easily reach, through the rotating operating window, the zones of the rectal mucous membrane corresponding to those envisaged by the Sias method for surgically treating haemorrhoids.

With reference to Figure 5, a prior-art dilator 20 is provided, said dilator being made of a material with a low attrition coefficient (e.g., Teflon) and which is shapingly coupled with the movable portion 6.

The operator uses the dilator 20 by positioning it inside the anoscope 1, when he inserts the latter through the anal region of a patient. The dilator 20 is shaped in such a way as to dilate the intestinal lumen to precede and facilitate the entry of the anoscope 1. Once the anoscope 1 has been located, the dilator 20 can be extracted, thus making the intestinal lumen accessible to the operator. Before the movable portion 6 is rotated, the dilator 20 is reinserted by the operator to relax the rectal mucous membrane and thereby facilitate said rotation.

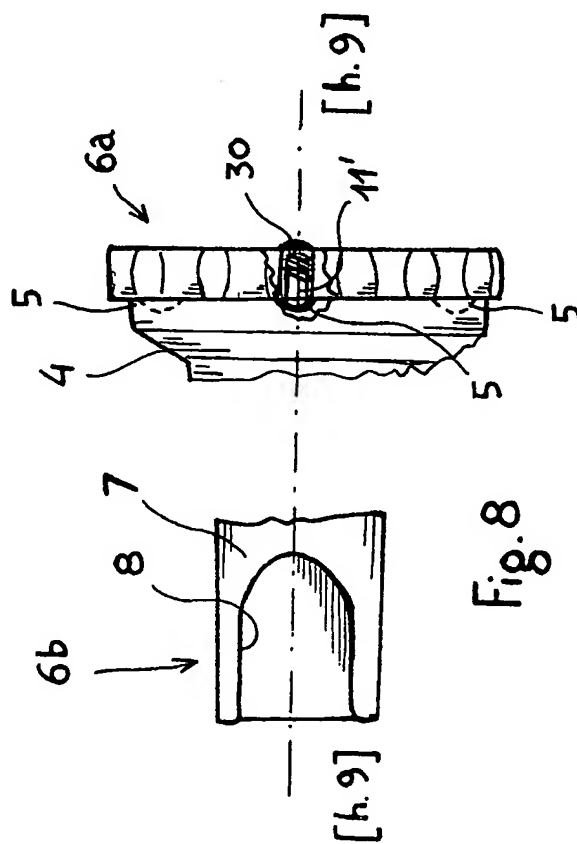
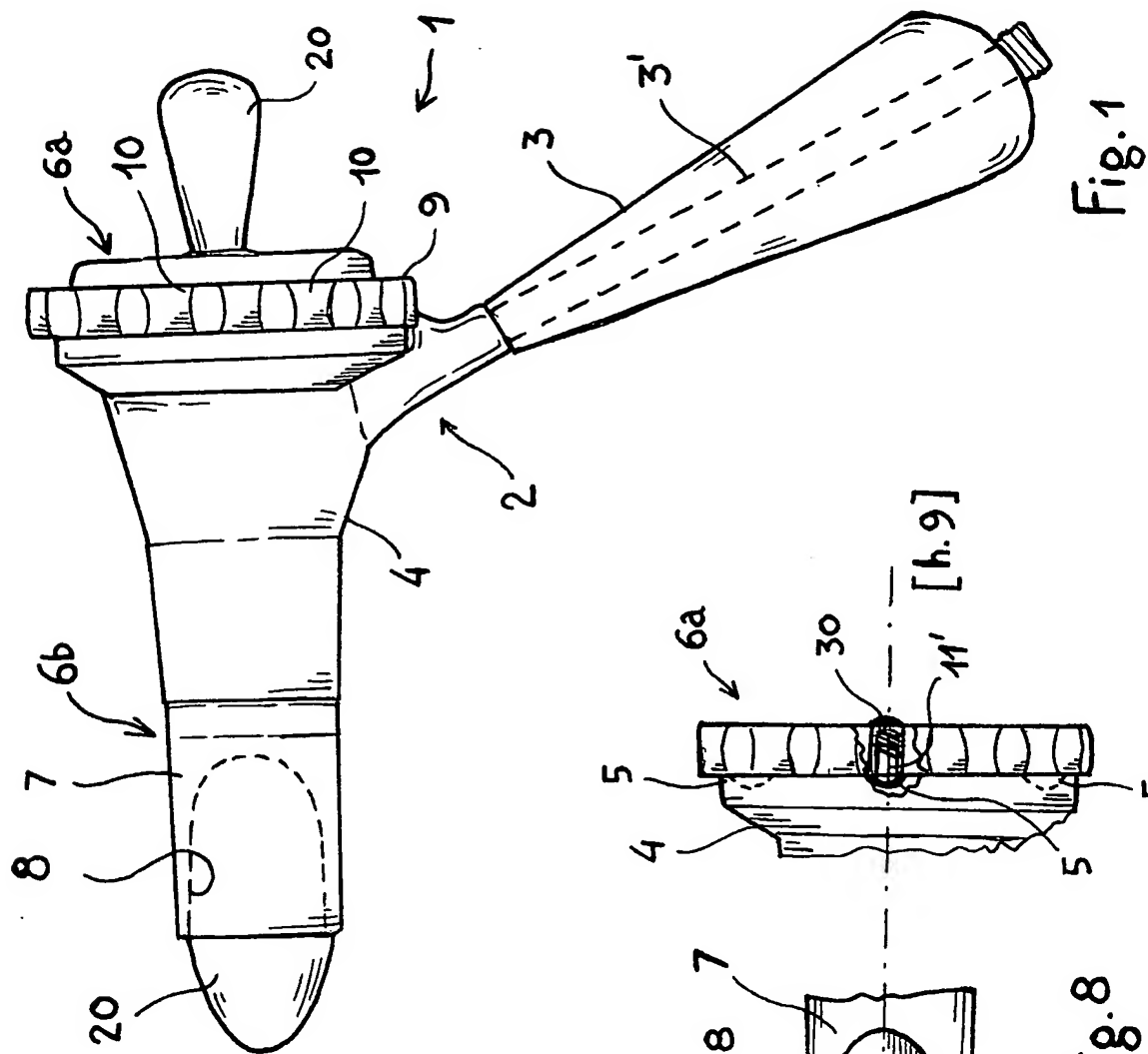
The anoscope 1, in addition to being used for carrying out the Sias surgical method, can be effectively used for: making elastic ligatures, cryotherapy, removing intestinal polyps, administering sclerosing injections, and carrying out diagnoses and transanal therapy in general.

CLAIMS

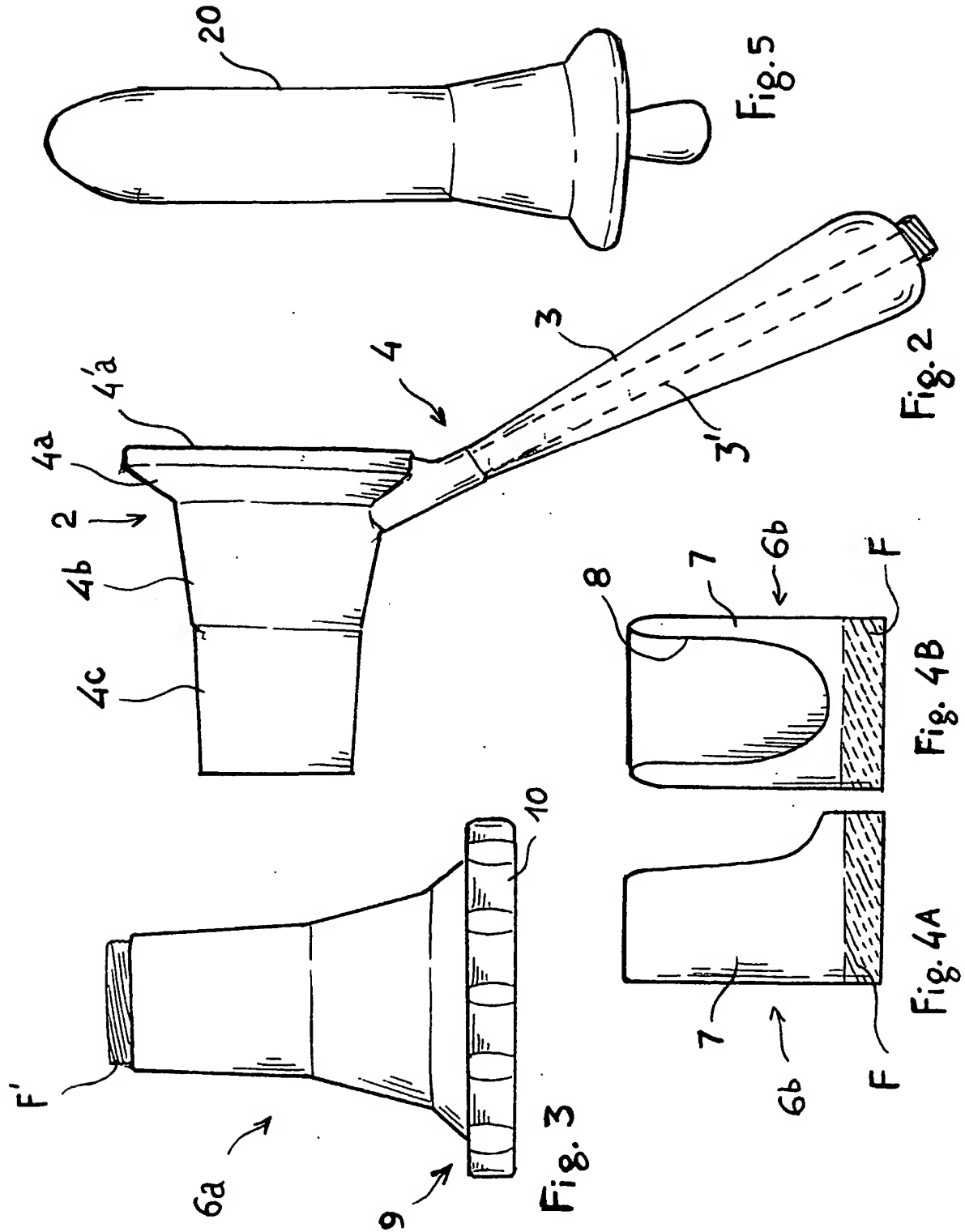
1. An anoscope (1), comprising a first hollow-body means (4) open at opposite ends and a second hollow-body means (6) open at opposite ends shapingly coupled with said first hollow-body means (4) and arranged to coaxially rotate inside said first hollow-body means (4), said second hollow-body means (6) being provided with a window means (8) arranged to make a portion of rectal mucous membrane accessible, characterised in that said window means (8) has dimensions and a shape such as to enable surgical means to intervene on said portion.
2. An anoscope according to claim 1, and furthermore comprising an angular positioning means (9) arranged to adjust the relative angular position of said second hollow-body means (6) in said first hollow-body means (4) in preset reciprocal angular positions.
3. An anoscope (1) comprising a first hollow-body means (4) open at opposite ends and a second hollow-body means (6) open at opposite ends shapingly coupled with said first hollow-body means (4) and arranged to coaxially rotate inside said first hollow-body means (4), said second hollow-body means (6) being provided with a window means (8) arranged to make a portion of rectal mucous membrane accessible, characterised in that angular positioning means (9) are also provided that are arranged to adjust the relative angular position of said second hollow-body means (6) in said first hollow-body means (4) in preset reciprocal angular positions.
4. An anoscope according to claim 3, wherein said window means (8) has dimensions and a shape such as to enable surgical means to intervene on said portion.
5. An anoscope according to any of preceding claims, wherein said first hollow-body means (4) comprises a first truncated-cone portion (4a).

6. An anoscope according to claim 5 wherein said first truncated-cone portion (4a) is solidly connected with a second truncated-cone portion (4b) that has a progressively decreasing cross-section.
- 5 7. An anoscope according to claim 5, or 6, wherein said second truncated-cone portion (4b) is solidly connected with a third truncated-cone portion (4c) that protrudes from a part opposite said first truncated-cone portion (4a) and has a progressively decreasing cross-section.
- 10 8. An anoscope according to any of preceding claims, wherein said first hollow-body means (2) has an edge (4'a) positioned in such a way that it faces the operator during use.
- 15 9. An anoscope according to any of preceding claims, wherein said second hollow-body means comprises a rotation segment (6a) and an operating segment (6b), that can be associated with one another before use.
10. An anoscope according to claim 9, wherein said window means (8) is arranged on said operating segment (6b).
- 20 11. An anoscope according to any of preceding claims, wherein said window means comprises an operating window (8).
12. An anoscope according to previous claim 11, wherein said operating window (8) is defined by a U-shaped cut.
- 25 13. An anoscope according to any of preceding claims, wherein said window means (8) opens near to the point that can be reached by the tip of an index finger of an hand of an individual of medium build, by inserting said index finger inside said second hollow-body means (6).
- 30 14. An anoscope according to any of preceding claims, wherein said first hollow-body means (2) comprises a grip element (3).

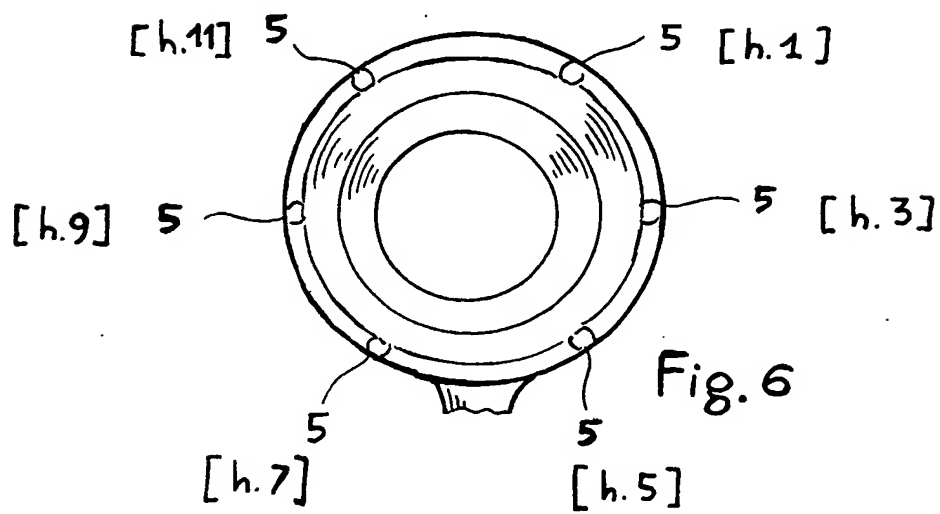
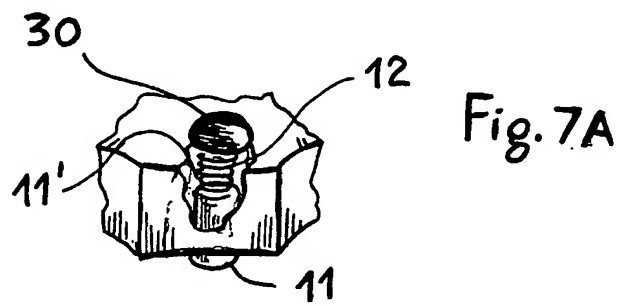
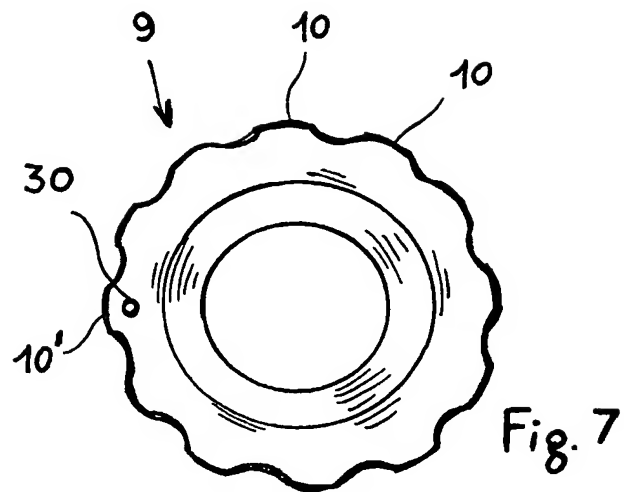
15. An anoscope according to any of claims 8 to 14, wherein said edge (4'a) comprises a plurality of notch means (5).
- 5 16. An anoscope according to claim 15, wherein said notch means (5) are 6 in number.
17. An anoscope according to claim 16, wherein said notch means (5) is arranged along said edge (4'a) according to the hours on an imaginary clock-face.
- 10 18. An anoscope according to claim 19, wherein said notch means (5) are arranged at 1 o'clock, 3 o'clock, 5 o'clock, 7 o'clock, 9 o'clock, 11 o'clock.
19. An anoscope according to any of claims 9 to 18, wherein said positioning element (9) is integral with said rotation segment (6a).
- 15 20. An anoscope according to claim 19, wherein said positioning element (9) comprises a plurality of tooth means (10).
21. An anoscope according to claim 20, wherein said plurality of tooth means (10) comprises a locking tooth (10').
- 20 22. An anoscope according to claim 21, wherein said locking tooth means (10) comprises a recess (11) housing a peg (11').
23. An anoscope according to claim 22, comprising an elastic means (12) interposed between said peg (11') and the bottom of said recess (11).
- 25 24. An anoscope according to any of claims 22 to 24, wherein the rotation of said positioning element (9) can be locked by an interaction between said peg (11') and each
- 30 of said notch means (5).

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3/3



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 464 412 A (BUDDING JACOBUS) 7 November 1995 (1995-11-07) abstract; figure	1
A	US 6 126 594 A (BAYER IZHACK) 3 October 2000 (2000-10-03) cited in the application abstract; figure 4	1
A	WO 01 43626 A (S S H MEDICAL LTD ;IBRAHIM NABEEL (AU); WEEGEN CLEMENS V D (AU)) 21 June 2001 (2001-06-21) abstract; figure 1	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5464412	A	07-11-1995	NONE	
US 6126594	A	03-10-2000	NONE	
WO 0143626	A	21-06-2001	WO 0143626 A1 AU 2127701 A	21-06-2001 25-06-2001